"THE EFFECT OF FISTULOTOMY WITH OR WITHOUT SETON ON ANAL PRESSURES AND CONTINENCE. USE OF ANAL MANOMETRY AND THE WEXNER SCORING SYSTEM"

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT OF THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY FOR THE DEGREE OF M.S. BRANCH I - GENERAL SURGERY EXAMINATION TO BE HELD IN SEPTEMBER-2008

CONTENTS

CERTIFICATE

This is to certify that "THE EFFECT OF FISTULOTOMY WITH OR WITHOUT SETON ON ANAL PRESSURES AND CONTINENCE. USE OF ANAL MANOMETRY AND THE WEXNER SCORING SYSTEM", submitted as a thesis for M.S. Degree Branch I – General Surgery examination of the Dr. M.G.R. Medical University of Tamil Nadu, is bonafide work of the candidate – **Dr. Tarun Jacob K John.**

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CERTIFICATE

This is to certify that the topic entitled "THE EFFECT OF FISTULOTOMY WITH OR WITHOUT SETON ON ANAL PRESSURES AND CONTINENCE. USE OF ANAL MANOMETRY AND THE WEXNER SCORING SYSTEM" is bonafide work done by **Dr. Tarun Jacob K. John**, post graduate in General Surgery at Christian Medical College, Vellore. This work has been carried under my guidance and supervision in partial fulfillment of the regulation of Dr. M.G.R. Medical University of Tamil Nadu for Master of Surgery- Branch I (General Surgery) examination to be held in September 2008.

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INTRODUCTION AND JUSTIFICATION

Fistula in ano is a common general surgical problem. There are a number of possible operative options available to the surgeon. Though a patient may not often report incontinence, it is a real and possible complication of all operative procedures described.

A practical, cost effective method of assessing incontinence is with incontinence scores. There are a number of such scores published. The anal manometer may prove to be a valuable adjunct in the pre operative assessment and post operative follow up of a patient with anorectal fistula.

There is paucity of Indian data on anal manometry in fistula in ano and this remains an area for further investigation[1,14].

AIMS AND OBJECTIVES

OF THE STUDY

- To determine the percentage of patients who suffer from impaired continence after anal fistula operations.

- Determine the predisposing factors that increase the risk of sphincter damage and incontinence.

- To identify a) those patients who are likely to sustain sphincter damage as well as b) those patients who will be successfully cured from disease without suffering sphincter damage.

PRESENT KNOWLEDGE FROM LITERATURE

5.1.1. History.

Surgery of anorectal fistula is referred to in the Ayurveda and dates from the time of Sushrutha 600 B.C. where the Sushrutha Samhita described a medicated seton *('KshaaraSootra')* in their treatment[12]. Instruments unearthed at Pompeii after the great eruption of Vesuvius in AD 79 suggest that laying open of anal fistulae was a procedure used at the time. Anorectal fistulae are one of the most common conditions seen by general surgeons. Despite this, recurrence and impaired continence are common. The complexity of successfully treating anorectal fistula resulted in the birth of colorectal surgery as a specialty in its own right.

5.1.2. Definition:

An anorectal fistula is a tract of granulation tissue that extends from the anorectum to the skin, usually in the perianal area. The Origin of the word is from Latin meaning a pipe or reed. The fistula may consist of primary or secondary tracts[5.] The word fistula is used in both the singular and pleural context in the English language.

5.1.3 Relevant anatomy of anal fistula.

It is important to understand the anatomy of the anal sphincters and the levator ani muscle complex, for a good understanding of anorectal fistula. These will be discussed below.

The anal sphincter is essentially made up of 2 muscles.

i) Internal anal sphincter.

ii) External anal sphincter.

The internal sphincter is the continuation of the inner circular smooth muscle of the rectal muscle wall and is under autonomic control (T10-L2, *Pelvic autonomic plexus*). It is about 3 mm thick and has a distinct lower border. Anatomical descriptions and fixed specimens may describe the internal sphincter to end proximal to the external sphincter. But in surgical practice the internal sphincter extends distal to the external sphincter in the anal canal[5].

The external sphincter is a circumferential tube of somatic muscle that lies around the internal sphincter. Anatomists conventionally teach three components of the external sphincter namely *subcutaneous, superficialis and profundus*. In clinical practice however, these three parts of the external sphincter are indistinguishable[37]. The puborectalis muscle of the levator ani complex is the uppermost part of the external

sphincter[39]. They are both under somatic control from the pudendal nerve (S2,3,4). There are various components of the anal sphincters as illustrated below (**Figure1**).

The outer longitudinal muscle layer of the rectum, pierces the lower external sphincter and attaches on to the perianal skin – *the conjoint longditudinal ligaments*. These septa are important in acute cryptoglandular sepsis, limited to the perianal region.

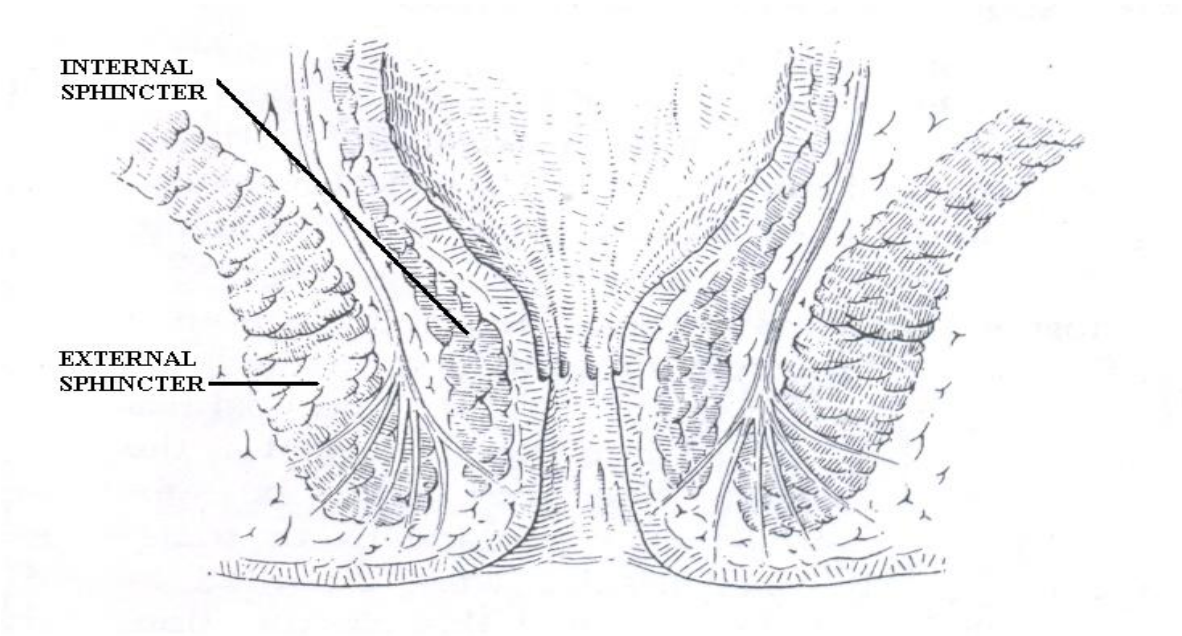


Fig 1. **Anatomy of the anal sphincters. Internal and external sphincters.** Reproduced with permission from Prof MRB Keighley (Surgery of the Anus, Rectum and Colon 3rd Ed. Saunders Elsevier)

The Levator Ani.

The levator ani is the pelvic diaphragm that separates the pelvis from the perineum. The muscles of the levator arise from the pelvic side walls. The vagina, rectum and urethra pass through this diaphragm, which surrounds them like a funnel. The levator was described first by Vesalius in 1555. The function of the muscle was described over a century ago by Holl[41]. Older authors commonly describe the Levator 'complex' to consist of the puborectalis, pubococcygeus, and Iliococcygeus[42]. The 'levator complex' theory proposed by Shafik and co-workers postulated that the levators contracted in the act of defecation (Isotonic contraction), and hence aided in defecation, lifting the anus up (cranially)[44,45]

Newer Concepts of levator function and morphology refute these claims and the puborectalis is no longer considered as being a part of the 'levator complex', based on dynamic MRI and morphological studies by Maolin and Dawei[39,40] . They used MRI, dynamic CT studies and cadaver dissection to show that the puborectalis is the only component of the three that contracts during squeeze and lifts up the anus. This muscle plays a major role in continence and not the levator basin, which actually relaxes *(physiological overstretching)* as a person defecates.[38]

5.1.4 Etiology of anorectal fistulae:

The anal glands are racemose glands that are situated in the anal canal. They are more seen toward the midline, and concentrated toward the *6 O' clock* position (lower midline). They secrete a type of mucous that is different from that produced in the rectum and have an unclear function. The anal glands are postulated to be the source of anorectal sepsis and subsequent fistulae. In fact, a number of the operative procedures describe its removal to reduce recurrence as the offending source of sepsis[5,2] .

The anal gland opens into anal crypts and open into the dentate line (or the pectinate line) of the anal canal. Anorectal sepsis may be associated with an inter-sphincteric, trans-sphincteric or supra-sphincteric suppurative process, secondary to an infected anal gland. Extra-sphincteric fistula are more often thought to be due to an intra abdominal cause or more commonly iatrogenic.

Other causes, though less common, are secondary to anorectal operations, tuberculosis, malignancy and Crohn's disease.

5.1.5 Clinical presentation of Anorectal sepsis:

Anorectal fistulae as explained above are the result of an infected anal gland. The usual acute presentation of the anal sepsis is in the form of an abscess. The anal gland usually lies traversing the internal sphincter and hence subsequent infection results in an inter-sphincteric abscess. This inter-sphincteric sepsis can spread in various anatomic planes, resulting in the different types of anal fistula. The 2 acute presentations in these events have been described below -

a) *A perianal abscess,* the inter-sphincteric sepsis is limited to the perianal area as the dense attachment in the fascia of the skin to the sphincter complex limits the spread of infection (Fig 1). These fistula usually result later in a chronic submucous or inter-sphincteric type of fistula.

b) *An ischiorectal abcess,* usually translating into a breach of the external sphincter, with sepsis having traveled into the fatty ischiorectal fossa (Fig 2). The isciorectal fossa on both sides, connect to each other via a space posterior to the anal canal and pre-sacral called *the retro sphincteric space of Courtney*. An ischiorectal abscess, will often mean a resultant trans-sphincteric tract of a subsequent fistula.

A mention of Goodsall's rule needs to be made at this juncture. Goodsall and Miles[20] stated that *'a fistula with an external opening anterior to a line drawn transversely through the centre of the anal orifice will follow a radial course directly to the dentate line. A fistula with an external opening posterior to this line will curve posteriorly to enter the crypt in the midline.'* It may be sufficient to say that Goodsall's rule is *not* always correct, and tends to be inaccurate in anterior fistula[2,5].

5.1.6 Classification of fistula:

Anorectal fistulae may transverse the muscular continence mechanism in varying degrees. The classification of fistulae is based on the anatomy of the fistula to its relation to the anal sphincters. These are illustrated by Prof. M.R.B Keighley[5] in the drawings below (Fig 2 -5, reproduced with permission).The various fistula described broadly fall into the following categories- Sub mucous, subcutaneous, inter sphincteric, high and low trans sphincteric, supra sphincteric and extra sphincteric[2,7]. The probability of incontinence increases with increasing amounts of divided sphincters.

Fistula types pictorially depicted[5]

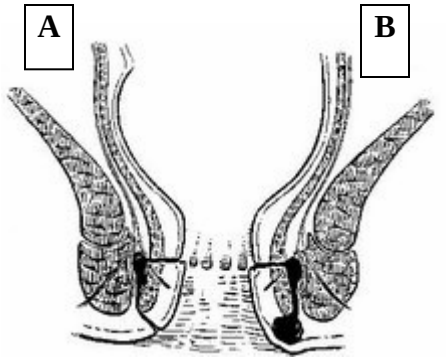


Fig 2. A simple **intersphincteric fistula** on the left hand side (A), and an inter sphincteric fistula with a perianal abcess on the right side (B)

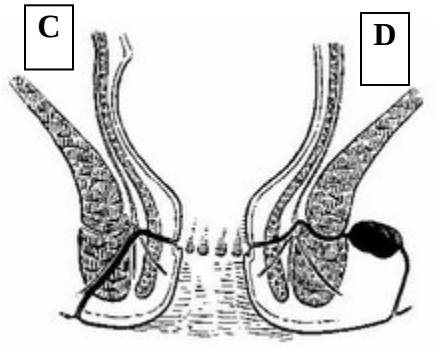


Fig 3. Trans-sphincteric fistula. A low trans-sphincteric fistula on the left side (C) and a high trans-sphincteric fistula with an ischiorectal abscess as described in the text on the right (D).

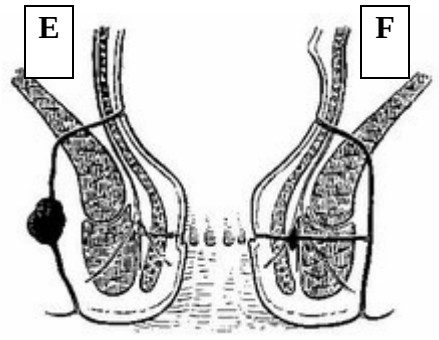


Fig 4. Extra-sphincteric fistula usually rare and iatrogenic. The figure (E), shows how an iatrogenic damage to the rectum occurs while draining an ischiorectal abscess. Fig 3(F) shows the common presentation of an iatrogenic extra-sphincteric complication of a trans-sphincteric fistula.

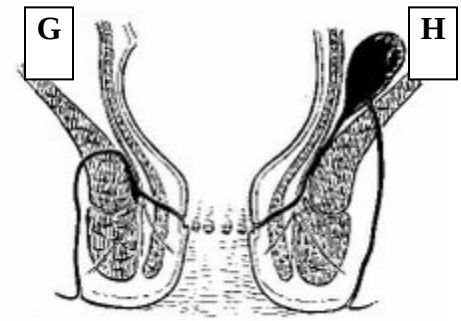


Fig 5. Supra-sphincteric fistula. Fig 4(G) Simple supra-sphincteric fistula. Fig 4 (H) shows the same complicated with a supra-sphincteric abscess.

5.1.7 Surgical options.

Fistula in ano may be an easy or exceptionally difficult disease for the general surgeon or colorectal specialist to treat successfully. Treatment must consider an appropriate balance between recurrence and impaired continence. The various options available for the surgeon are discussed below – but are all associated with varying degrees of potential recurrence and impaired continence[2,8]

The most common surgical treatment options for anorectal fistula are

a) To lay open the fistula tract (**Fistulotomy**). This can be done using various methods- cold knife, electrocautery (most commonly used) and a radiofrequency probe[22] are described in literature.

b) To place a **seton** through the fistula tract to

b(i) slowly divide the tissue above the fistula or

b(ii) to act as a drain to control sepsis alone.

B(iii) To act as a specialized variant in seton techniques such as internal anal sphincter sparing seton, where a randomized controlled trial by Zbar and co-workers showed [28]better sphincter manometry pressures, when compared to a cutting seton. There

was however no statistically significant change in incontinence scores.

c) To primarily remove the fistula (**fistulectomy**) and

c(i) repair the defect in the muscle and the anus with an *anorectal myo- mucosal advancement flap*. [5]

c(ii) To close down the raw area with a technique of marsupializtion, that results in faster wound healing rates as described in by randomized controlled trials by Pescatori and co-workers and Ho and co-workers. [29,30]

d) Fibrin glue has been used for the last 2 decades or so[2]. As a result there are a number of publications on their use and indications since the early 1980's. Fibrinogen, factor XII, fibronectin and aprotinin, are the active components. This can be prepared in an autologous manner from the patient's own blood or used from commercially available preparations[23,24]. Their use has been limited in India due to the high cost.

e) Collagen plugs are a recent development in the treatment of anorectal fistula. The plug is made from lyophilized porcine intestinal collagen. Long term studies are still not available for recommendations to be made on its use. [2,25,26]

f) The Kshaarasootra is the term for ayurvedic medicated cutting thread, used for treatment of anal fistula. The thread is prepared on 20 G surgical linen. The thread is coated with latex of E.neriifolia, ash and turmeric powder. The *p*H is 9.75 – the thread is sterilized in UV light and is about 25 cm long. The thread needs to be changed on a weekly or fortnightly basis until healing. The alkaline nature and inflammatory response the chemicals evoke are thought to be the cause for its success[1,].

Optimum surgical treatment for anorectal fistulae is one that is associated with low recurrence rates and minimal anal incontinence.

5.2 FECAL INCONTINENCE:

There are no clear guidelines as to the best possible procedure for a fistula in ano, and this question has been the question of focus in a recent meta-analysis protocol[15]. However, the published incontinence rates of different procedures vary. Patients may not be very forthcoming in their expression of impaired continence. There is a need for an effective subjective and objective method to evaluate the prevalence of impaired continence. Probably, the only satisfactory method is the use of standard

accepted incontinence scores, which will assess the presence and frequency of the following parameters before and after fistula surgery

- Flatus incontinence
- Soiling
- Urgency
- Urge incontinence
- Liquid stool incontinence
- Solid stool incontinence

Incontinence may mean different things to different persons. To a patient the inability to control flatus may be socially debilitating. However the medical practitioner may only enquire about stool soiling, solid or liquid stool incontinence and may even ignore urgency. Iatrogenic incontinence is a difficult condition for a patient to accept from what was presumed to be a simple operation. Impaired bowel continence can cause a devastating impact on social and sexual life.

5.2.2. INCONTINENCE SCORES:

Scoring systems for Incontinence

The literature has a number of possible scoring systems for evaluation of incontinence. [9,3]

- The Pescatori score
- The Wexner score
- The American Medical Systems score
- The Kamm Score

The above are a few examples of commonly used scoring systems that are used to evaluate incontinence. These scoring systems look at various aspects of incontinence such as lifestyle modification, leakage of solid stools, liquid stools or flatus. The first incontinence score was devised by Browning and Parks and published in 1983. There have been a number of scoring methods proposed since then.

Incontinence scores are an effective way to quantify and follow up of the severity of incontinence in a patient. Incontinence scores can be used independent of the operation performed.

Two of these scores (The Wexner and The American medical systems score) are displayed in the appendix 1 and appendix 2 at the end of the dissertation. These scores give the assessor a set of questions that

are reproducible and objective. There are many publications that justify the use of various scoring systems. In fact Vaizey and co-workers devised a score that correlated well to both clinical examination and to other scores. This is called the Kamm score. The use of anti-motility agents is graded in this score. [6,9].

Incontinence scores record the extent to which bowel incontinence impact on life style and quality of life. The WEXNER score, used in this study has been discussed.

The Wexner score:

The Wexner score is a scoring system that ranges from 0 (complete continence) to 20 (complete incontinence). The score is easy and not society specific. There is a small component of the score that assesses lifestyle alterations, hence incorporating a quality of life assessment. The questions are about use of pads, life style modifications and incontinence to solid, liquid or flatus. These are scored based on their frequency – monthly, weekly or daily. The table for this score has been given later (appendix-1).

MANOMETRY for incontinence:

Anal manometry is an objective means of measuring both resting anal tone, largely derived from the internal anal sphincter(IAS) activity (smooth muscle under autonomic activity) and squeeze pressures, a reflection of external anal sphincter (EAS) activity (striated muscle under voluntary control) [10,11]. This may correlate with the degree of bowel incontinence and improvement or worsening of sphincter function. Anal manometry can also be used for the measurement of the presence and depth of the R.A.I.R (Rectoanal Inhibitory reflex), amongst other things. Its ability to separate internal anal sphincter and external anal sphincter functions has been utilized in this dissertation and correlated with symptoms (internal anal sphincter: flatus and soiling, external anal sphincter – urgency and urge incontinence). Anal manometry also allows for the assessment of the functioning length of the anal canal. [36,] these have been discussed in detail later.

5.2.3 Incontinence after fistula surgery:

Fistula surgery aims to cure the fistula while maintaining continence. Continence can be regarded as the balance between rectal pressures and the power of the sphincters to withstand this.

Incontinence following conventional fistula surgery is common. In Indian patients, fistula in ano form nearly 1.6 per cent of all surgical hospital admissions[14], many more are performed as office or day care procedures. Many patients are so relieved by the symptoms of their disease that they do not actively complain of a mild incontinence, whereas a detailed questionnaire would pick up minor degrees of bowel incontinence. Occasional soiling of liquid stool on undergarments or infrequent flatus incontinence may escape the patient's memory, as it does not always disturb them. A routine history and clinical examination will not pick up the actual number patients with altered continence, but as Vaizey and co-workers published, a good scoring system would correlate with an experienced clinical investigator's assessment of improvement. [6,9]

A study in St. Mark's hospital, London revealed that up to 31 percent of patients have soiling post surgery for fistula in ano. Indian studies report a much lower (5.4%) incidence. However one must note that there is scarce data in Indian literature[4].

Evaluating the incidence and severity of fecal incontinence can be a difficult task. Incontinence scoring has been of proven value in clinical trials and in the follow up of patients with incontinence. The WEXNER

score has been chosen in this study for its simplicity and accuracy as a scoring system.

Manometry may have a protective role in those patients having anorectal fistulae operations. Mylonakis and co-workers showed that anal manometry before fistula surgery can improve the outcome in patients especially, women above 50 years. Knowledge of their sphincter function improves the functional outcome in such patients[6]. The surgeon may choose a more conservative approach in a patient who has poor manometry, such as a core out-advancement flap or placement of a seton – rather than laying open the fistula and damaging the sphincters.

A review of 624 patients in Minnesota Medical School by Garcia-Aguliar and co-workers, examined the factors that are associated with post operative fecal incontinence and recurrence after fistula surgery[17]. The study was a retrospective analysis that examined fistula type and risk factors. The factors identified in their findings, that were associated with *recurrence* were (i) complexity of the fistula,(ii) internal opening identification and (iii) type of procedure adopted. The predictors of *incontinence* were identified in 56% of patients who underwent fistula surgery. The duration of follow up was 2.5 months, with the most continence disorders in the first 2 weeks of surgery. Female gender was a

strong predictor of post operative fecal incontinence. Other predictors found were complex type of fistula, increasing amounts of external sphincter involved by the fistula tract, and treatment by 2 stage or cutting fistulotomy were associated with incontinence. The female patient in fistula surgery is always a concern, because of a possibly weak sphincter due to child birth. This has been studied in detail by Sultan and co-workers and other authors have frequently demonstrated continence dysfunction after vaginal deliveries[18,46,47]. These observations were taken into consideration while deciding the exclusion criteria for this prospective study.

Another retrospective study, using a questionnaire to quantify bowel incontinence examined the various factors influencing incontinence after fistula surgery. In their study, W F Van Tets, Kuijpers and co-workers from Netherlands (University Hospital Nijmegen), analyzed factors which might predict continence disorders. The study showed a higher rate of bowel incontinence in patients with high internal openings, posterior fistula and horizontal tracts. Bowel incontinence was measured using a symptom scale (not a scoring system) and the patients were classified as continent and those with impaired continence[16].

5.2.4 Factors affecting bowel continence.

There are a number of factors that determine continence apart from the integrity and the function of the internal and external sphincters. These include factors such as the physical nature of the stool and the innervation of the sphincters. The physical integrity of the anal sphincters is thought by some to be the most important factor in maintaining continence, and hence there is an interest in primary repair in anal sphincter trauma[46].

5.3 ANAL MANOMETRY.

5.3.1 Measurement of anal pressure.

Anal manometry is an objective method of recording anal pressures. It provides data on the length of the anal canal as well as resting and squeeze pressures[5].

The anal manometer records anal pressures –traditionally this is done at 1 cm intervals in the anal canal. The newer and more sensitive catheters can record pressures at 0.75cm intervals. The diameter of the recording device should be no larger than 5 mm to prevent falsely high anal pressures.

There are a number of systems measuring anal pressure. All anorectal manometers can be divided into two major **components**. [35]

(i) An intra anal or intra rectal pressure sensing device – microballoon, a microtransducer or a water perfused catheter.

(ii) The above is connected via a pressure transducer to a recording device – a polygraph or a computer.

The **technique** of manometry can vary. The intra-anal pressure recording catheter can be;

(a) Left in the same position (*stationary technique)* for recording

(b) Manually moved at constant intervals *(manual or station pull through technique)*

(c) Continuously or automatically withdrawn (*continuous or automated pull through method)*

Manometry systems.

1. Perfusion systems - Readings is based on a constant perfusion of about 0.3 ml/min of water into a soft noncompliant catheter. The principle of this technique is based on the measurement of resistance in terms of pressure that the sphincters offer to a constant flow of water through the port.

Multiple channels may be placed in the same catheter, to obtain simultaneous readings.

2. Balloon systems – Early balloons were about 1 cm, the micro-balloons (diameter 4mm) are more accurate. These balloons can be air or water filled and transmit pressures in a noncompliant tubing to transducers. These need station pull through technique for recording.
3. Sleeve catheters / Strain gauge catheters – are other available recorders. The latter being a solid state device, and based on the cantilever and a semiconductor set in a resistance bridge.

When data is fed into a computer, the pressures can be reconstructed in a 3 dimensional manner, and hence pressure vector volumes are created if multiple spatial recordings are available. Computers have replaced the polygraph output machines in new generation anorectal manometers. [36]

5.3.3 Sphincter component testing:

The internal anal sphincter is a smooth muscle fiber under constant electrical activity from the autonomic nervous system. This is responsible for anal tone which maintains the anal canal closed at rest. Hence this is a

sphincter that is not under voluntary control. The other muscles of continence are the external anal sphincter and the Puborectalis muscle. These are voluntary skeletal muscles and are innervated by the sacral nerve and the pudendal nerve. There is newer data to suggest that the external sphincter alone does not contribute to the squeeze pressures of the anal canal and this may be contributed to by the puborectalis muscle that contributes in the upper anal canal[19].

Resting anal tone is contributed chiefly by the internal anal sphincter (75- 80%) and also by the external sphincter complex. Resting tone is responsible for keeping the sphincters closed at rest. The internal sphincter is assessed by placing the manometry probe in the anal canal and waiting until the pressures stabilize (1 to 3 min). The resting anal tone is then measured. The internal sphincter function can be measured in this way, along with High pressure zone measurement and Recto-anal inhibitory reflex, discussed below. It is known that the resting pressure can be raised in conditions like hemorrhoids and anal fissure. The hemorrhoidal cushions have a role to play in the resting anal tone.

The external sphincter is assessed mainly by squeeze pressures. The external sphincter and puborectalis are able to contract on a voluntary basis and maximal squeeze pressures are obtained at different levels in

the anal canal. The external sphincter contributes very minimally to the resting tone, and this is not used to assess its function.

5.3.4(a) The Recto-anal inhibitory reflex

The internal anal sphincter is an involuntary muscle that is contracted under basal conditions. The muscle relaxes as a reflex to rectal distention and hence allows the anal mucosa to sample the contents of the rectum. This concept forms the basis of the Recto-anal inhibitory reflex. The recto-anal inhibitory reflex is tested by placing the probe of the anal manometer in the anal canal and distending the rectum with a balloon after a baseline resting anal pressure is measured. A precipitous fall is seen on the graph paper as the sphincter relaxes with rectal distention and then contracts again. This reflex is lost in Hirschprungs disease, where segments of bowel are tonically contracted where intrinsic innervation has failed to develop. Some investigators have used this principle as a test for the internal anal sphincter function[36].

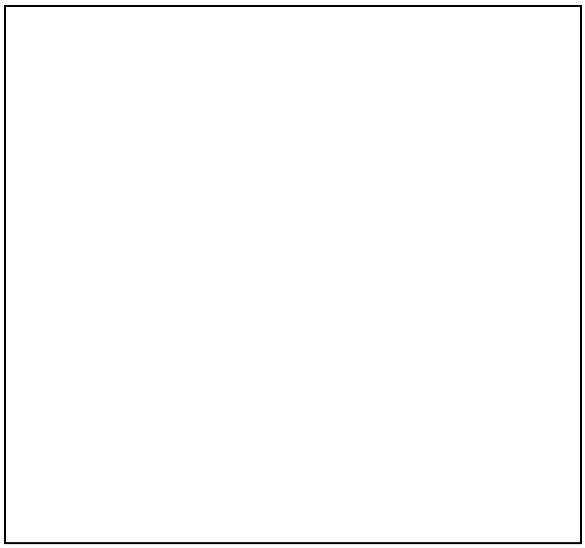


Figure 6 – A photograph of a graph from our physiology lab, demonstrating a recto-anal inhibitory reflex.

The external anal sphincter can be tested by anal pressure measurements assessing squeeze pressure. The external sphincter is under somatic control (pudendal nerve) and hence is a voluntary muscle. The patient is first assessed by a rectal examination, and coached to squeeze against the examiners finger and do a similar maneuver when the manometer probe is inserted.

5.3.4(b) Concept of anal High Pressure Zone (HPZ).

There is a concept of the anal high pressure zone. This is very simply the length of the anal canal, where a resting anal pressure can be measured. The HPZ, gives an idea of the length of the anal canal, before the manometric probe enters the rectum. The rectal pressures are about 5 – 10 cm of water, and are apparent when the pressure transducer readings precipitously fall from a resting tone of 60cms +/- 10 cm of water, the normal anal pressure. The normal length of the anal HPZ is 3 – 5 cm. These are important in planning colo-anal anastomosis, pouch procedures and may be useful in the evaluation of impaired bowel continence. [35]

5.3.5 Applications of anal manometry:

The anal manometer has multiple applications in clinical practice. It is used in assessment of fecal incontinence, chronic constipation and in preoperative assessment in patients who are to undergo operations such as[35].

i. A low colorectal anastomosis
ii. Coloanal anastomosis
iii. Ileoanal anastomosis
iv. Fistula surgery

v. Fissure surgery if AIDS related or recurrent anal fissure after sphincterotomy.

The references in relation to the use in fistula in ano are few and with small study populations[9, 21, 28]. Zbar and co-workers had recruited 34 patients with anal fistula into 2 procedure groups and followed them up with manometry. The change in either resting or squeeze pressures in these groups were of no statistical significance. Sentovich and co-workers studied anal sphincter morphology with anal manometry and transanal ultrasound on 31 women planned for sphincteroplasty compared to an asymptomatic population of 2 groups of nulliparous and parous women. This paper showed that anal manometry was able to identify lower sphincter pressures and length of HPZ in those women already planned for a sphincteroplasty, hence highlighting the use of anal manometer in incontinence evaluation.[11] Mylonakis and co-workers recruited 100 patients and performed preoperative anal manometry before various operations for fistula in ano. He feels that preoperative manometry is important in determining the type of operation for anorectal fistulae. His patient population was of the non-complex fistula type of which seven patients who would have normally had a lay open

procedure were treated with a seton due to low preoperative resting pressures.[6]

There is a scarcity of data from the Indian subcontinent on anal physiology and there is potential for further studies in our population.

PATIENTS

AND

METHODS

Patients:

Consecutive patients that presented to the general surgery department with fistula in ano were recruited for the study. The protocol and research methodology was cleared by the institutional research committee, before the study was begun. The aims and purpose of the study were explained to the patient and informed consent was obtained before enrolment. The informed consent document is presented at the end of this dissertation in APPENDIX 5.

Patients were recruited from August 2005 – Feb 2008 (A period of approximately 30 months). There were a total of 224 patients that were recruited for the study. The follow up rate was 25%, with 57 patients completing both preoperative and post operative assessments.

The following **inclusion criteria** were used for the recruitment of patients into the study

- All patients presenting to the Christian Medical College with a fistula in ano. This included patients referred from the peripheral clinics of the hospital.

- Any patient in whom the presence of a fistula had been confirmed by a consultant in General surgery.

- Any patient with recurrent disease or those with a seton in situ were included in the study.

- Patients with non crypto-glandular origin such as Crohn's disease and tuberculosis were still included in the study, but identified and classified as such.

Patients who were unable to attend follow up due to distance and travel concerns were not included into the study though their anal pressures and incontinence scores were documented in a separate departmental protocol. The data on such patients are not included in this dissertation for analysis or discussion.

The following <u>exclusion criteria</u> were followed:

- All patients with a coexisting anal fissure were excluded from the study in view of discomfort caused by anal manometry.

- Those unable to attend follow up 3 months after the start of the study were excluded.

- Elderly patients over the age of 65 were excluded from the study as it was felt that they may have atrophic sphincters and this may confuse the data.

- Women whose parity was 4 or more were excluded from the study because of possible sphincter and pelvic floor weakness.

- Patients with diagnosed or demonstrable sphincter injuries from trauma, previous fistula surgery and obstetric injury were excluded from the study.

- Neurological disorders involving the innervation of the sphincters or pelvic floor were excluded.

DATA COLLECTION:

The following details were noted, the pro-forma used is attached as an appendix to the dissertation (APPENDIX 5).

Hospital details.

Demographic data – Sex, age and address.

The type of fistula

The past history of surgical intervention.

Notes / diagram of the tract if possible.

Incontinence score (Wexner).

Relevant clinical data – including interesting local specific practices such as use of cloth / pads as a response to incontinence.

Social problems if volunteered.

All patients recruited for this study underwent a similar procedure both pre and post operatively.

Anal manometry: Anal pressures were measured at 1,2,3,4 and 5 cm from the anal verge. Parameters studied were pressures at rest, maximal squeeze effort and cough pressures. The Hancock's method was used for the manometry. The pressures were recorded on heat sensitive paper via a pressure transducer. The actual pressures were calculated after standardizing pressure at 100 cm's of water. All pressures were recorded in cm of H_20. The length of the anal canal HPZ (High pressure Zone) was assessed from the length of anal canal (where resting pressure greater than rectal pressure was recorded). A precipitous fall of resting pressure was associated with the placement of the pressure recording balloon beyond the anal canal into the rectum.

SAMPLE SIZE CALCULATIONS.

The results of this study are mainly descriptive, so as to determine the functional outcomes and look objectively at the data produced over this period of follow up.

Determination of sample size for this study would require the prevalence rate of incontinence in the community after a fistula operation. This prevalence would be required to sufficiently power a study to show statistical significance or effect.

A number of studies were considered[1,2,4,6], when proposing the prevalence of incontinence in patients with anorectal fistula. It needs to be emphasized that different procedures result in different incontinence rates. Studies that involved impaired continence rates with procedures like Fibrin glue, or anal advancement flap procedures were not used as these are not commonly used in our institution and good Indian data is not available. It may be also safe to state that the incontinence rates are not as high as a fistulotomy. The St. Marks hospital has reported an incontinence to loose stool of up to 17% in their series of 793 patients

undergoing various operations[4]. A study closer to home and perhaps more relevant was chosen, done by the ICMR reporting the percentage of incontinence at **5.4%** (13/235 patients) [1]

The sample size to be able to confer a 3% precision would be according to the formula - **4 * p q / d** [2].

Where, - p is prevalence of incontinence post conventional fistula surgery q = 100 – p

d is the expected precision of the study

If the above formula was used and the values substituted as below

4 x 5.4(prevalence of impaired continence) *** (100-5.4) / (3 x 3)** study precision

Sample size = 231 patients. (for a 3% precision)

DATA

ANALYSIS

SPSS ® (11.0 for windows; SPSS inc., Chicago, IL) was used for analysis of data. Patient recruitment was as described above, in keeping with inclusion / exclusion criteria. The following data was obtained from patients that presented with anorectal fistula in the out patient department.

BASELINE DEMOGRAPHICS

Total number of cases recruited for the trial – 224

Total number of cases that completed follow up (3 months or more) = 57

Loss to follow up rate – 75%

Mean follow up duration – 3.9 months. Range (3 months – 11 months)

Male patients – 54 out of a total of 57

Female patients 3 out of a total of 57

Average age of the patients recruited – 42.6 years.

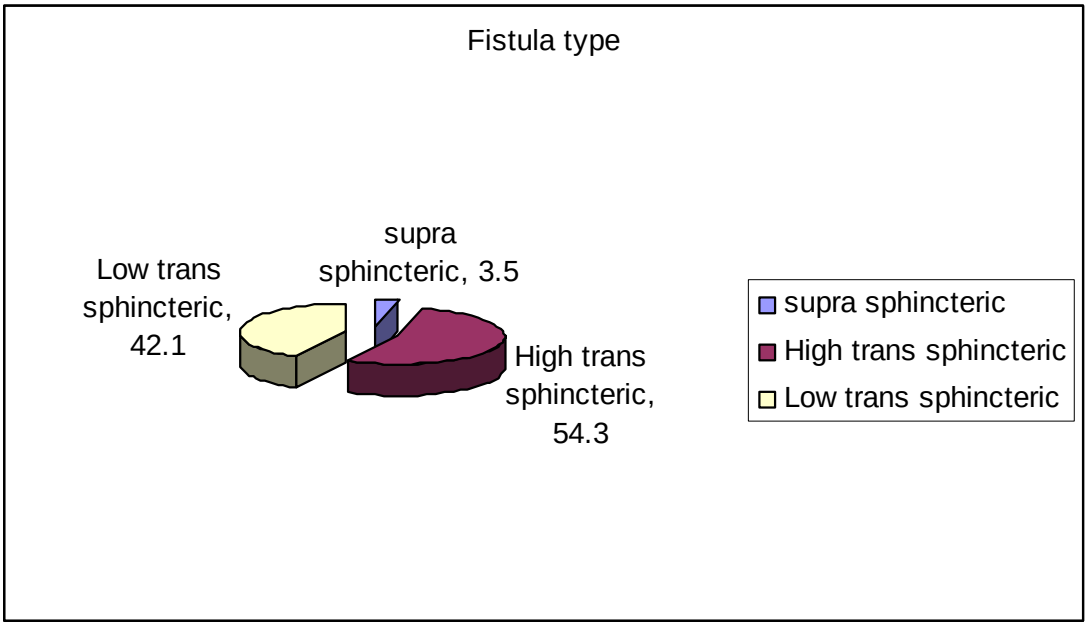
Cases with biopsy / culture proven Tuberculosis – 5.2%

Data was analyzed from detailed spread sheets, made using data from the data entry sheets. The salient data of recruitment and demography are given in the bullets above.

Analysis of the data revealed the following information.

Type of Fistula:

The fistulae were classified by the Parks classification as described elsewhere. There were a total of 57 patients. 2 Fistulae were supra sphincteric and 55 were trans sphincteric. Of the 55 that were trans sphincteric 31 were high trans sphincteric and 24 were low trans sphincteric. The types of fistula have been graphically represented below.



Previous operations:

As a tertiary referral center it is important to define the number of patients that present for re-operations. The initial anal pressures may be affected by previous operations for anorectal fistula. Thirty patients out of 57 were operated with either a fistulotomy, fistulectomy or a seton placement before they were recruited for this study, contributing to a 52% baseline recurrent fistula population.

Choice of present operation:

The patients in this thesis, when analyzed underwent the following operations – Seton insertion or fistulotomy. There were no patients with other procedures, such as advancement flaps or marsupialization.

All patients with a high trans sphincteric fistula (defined as involvement of 50% or more of the sphincter), were treated with a seton. There were 31 patients in this group and all had a seton placed. The 24 patients that had low trans sphincteric fistula were treated with setons in 13 and fistulotomy in 11 cases.

A lot of patients in this study have had a seton inserted. Two possible explanations for this high number are:

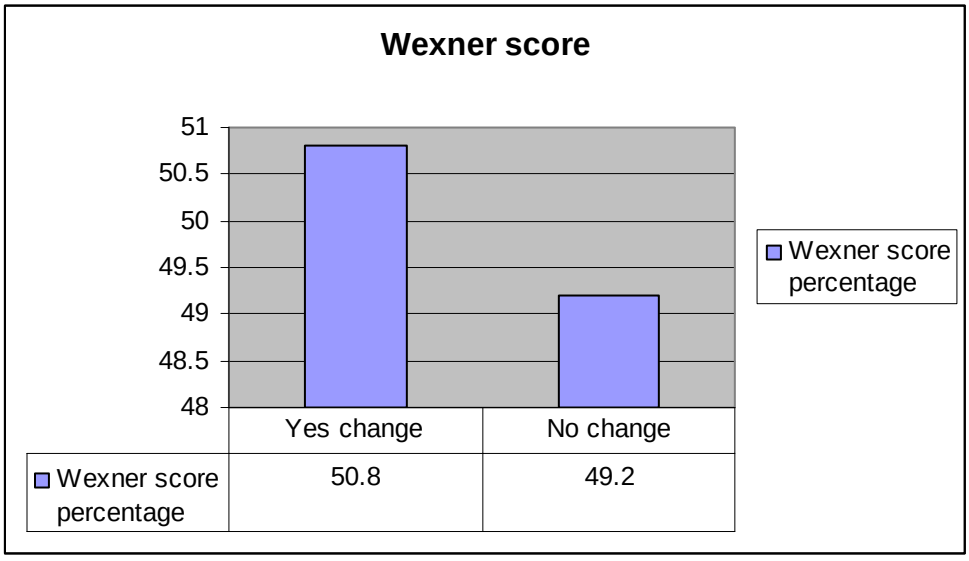
1) A large loss to follow up (75%). Patients cured by fistulotomy or fistulectomy would not have returned for follow up, and hence the follow up population has a large number of patients with setons in situ.

2) The large number of recurrent fistulae (52%) will mean a fear of some degree of sphincter compromise. Hence the surgeons in question would have erred on the side of conservation of as much as sphincter as possible by way of placing setons.

ANALYSIS OF WEXNER SCORE DATA:

The Wexner score as described earlier was used for scoring of patients, both pre operatively as well as post operatively. Patients were either classified as having no change in the Wexner score or having had a change in the score. A single patient was found to have an improvement in his incontinence score post operatively. This was looked at in detail. It was thought to be due to the fact that he had multiple external openings and ischio-rectal sepsis that kept him wet and uncomfortable, hence simulating leakage. This reveals a fallacy of this particular score.

The percentage of patients with a change in Wexner is shown below as simple bar diagrams.



The baseline range of values on the Wexner score were **from 0 (no change) to 8**. (Where a score of 20 would indicate complete incontinence). The change in Wexner score was noted between pre and post operation.

This is an important finding to note, indicating that 50.8% of all patients presenting after operations for fistula in ano, suffer some degree of impaired continence.

STATISTICAL ANALYSIS OF ANAL PRESSURES

Analysis of Anal pressure studies:

The results of the anal pressure studies reveal the following results.

Mean pressures:

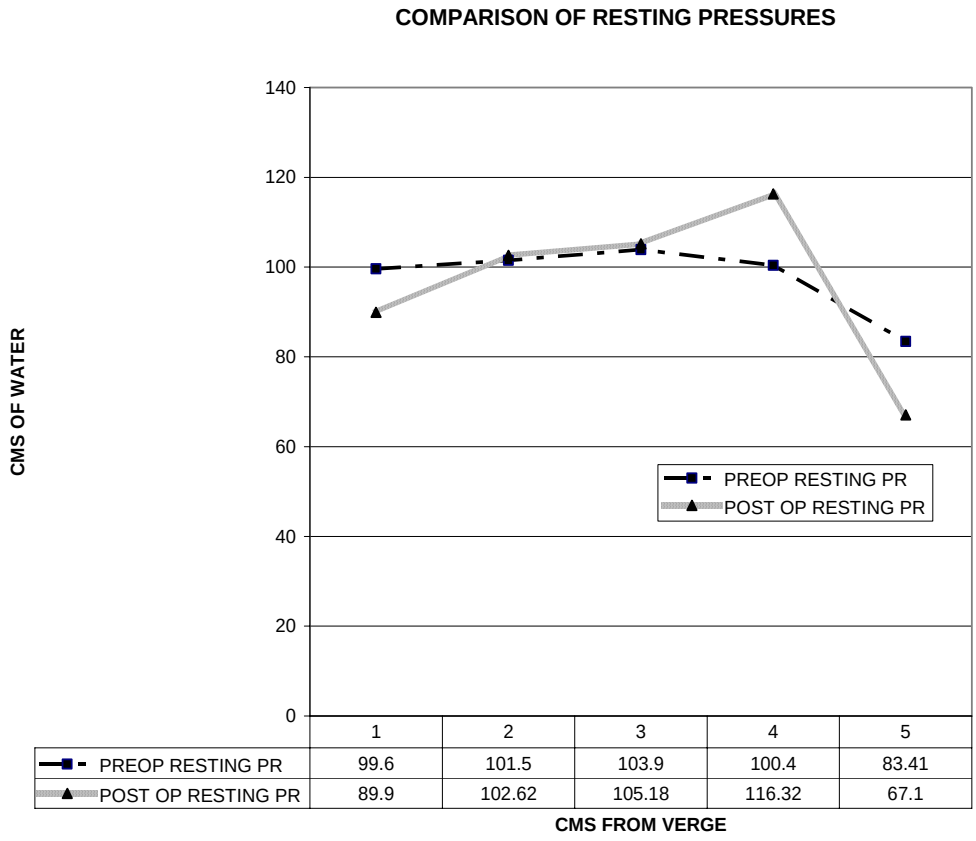
When mean pressures were analyzed in the study group,

i) Mean resting pressures were plotted on a graph from 1 to 5 cm along the High pressure zone (HPZ). The same was done for mean squeeze pressures. On comparing values (Graph 1 and Graph 2) there seemed to be an increase at 4cms. This was tested statistically and the change in squeeze pressure was found to be significant. (p value <0.001, by Wilcoxon signed rank test(a parallel non parametric test))

ii) There is a **drop in resting anal pressures of 8 cm of water** between pre operative and post operative values. The resting mean sphincter pressure preoperatively was 136 (SD 50) cm water and post operatively was 128 (SD 35) cm water.

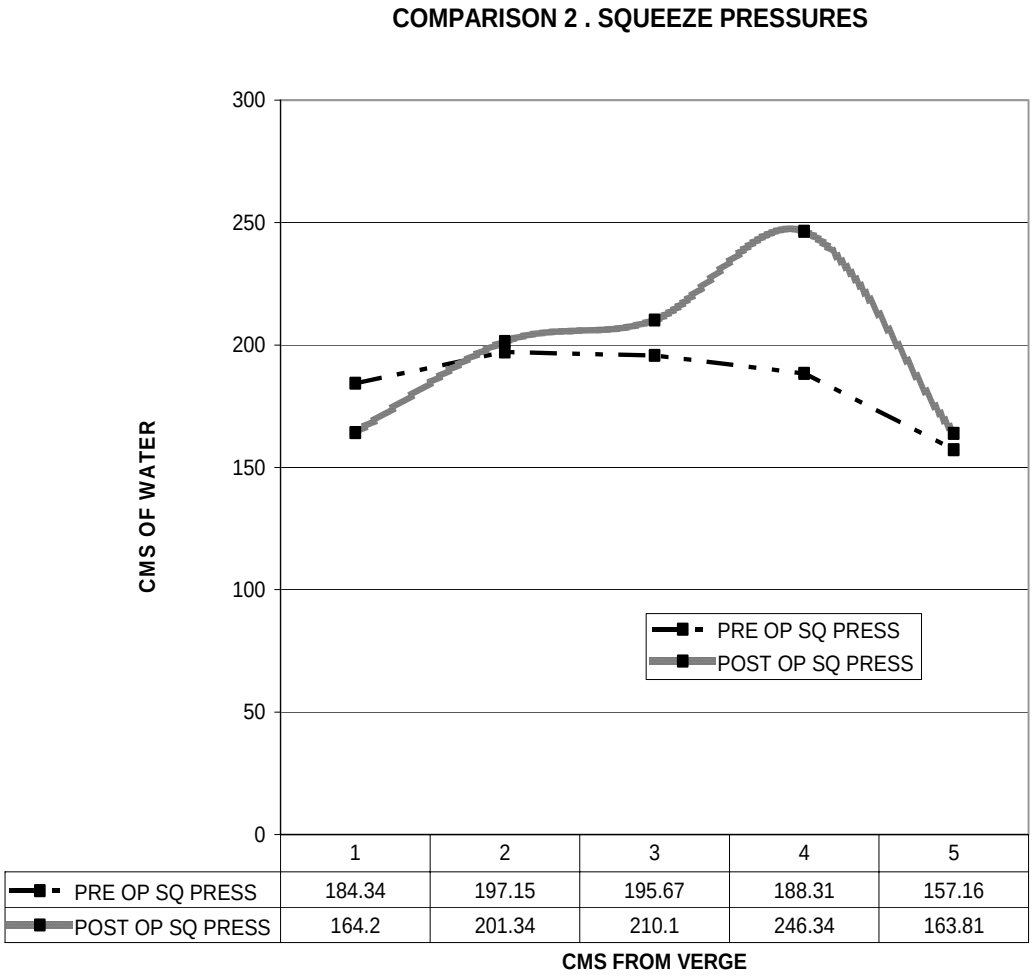
iii) The **maximum squeeze pressure increases by 4 cm of water** between pre operative and post operative values. The Maximal squeeze pressure (MSP) preoperatively was 239 (SD 89) cm water and post operatively 243 (SD 70) cm water.

Graph 1: **Graph depicting the difference between pre operative and post operative resting pressures.**



	1	2	3	4	5
PREOP RESTING PR	99.6	101.5	103.9	100.4	83.41
POST OP RESTING PR	89.9	102.62	105.18	116.32	67.1

<u>Graph 2.</u>Graph, depicting the difference between preoperative and post operative squeeze pressures.



Quality of life / social performance analysis:

During the study, all patients were asked a simple question. “Are you able to function socially after the operation?” This is a relevant observation, since in certain populations a minor degree of impaired continence may not affect their social lives. Many patients, especially in eastern societies do not find incontinence to flatus an embarrassing event.

If the manometer and Wexner score declare a patient incontinent, the quality of life the patient leads post operatively may be just as good, if not better than he was pre operatively. This question was put in so as to see where the studied parameters (manometry and scores) stood in relation to patients opinion of a problem.

When the data was analyzed it was seen that 12.2% of patients (7 patients out of the 57) were socially affected by the operation. This means the operation affected their quality of life in some form. For example, one patient was using torn cloth to pad his undergarments and prevent soiling. Another claimed that he was unable to ride a bicycle, due to pain at the scar site of surgery, and the shearing causing stool to leak out. Three others found the inability to control flatus disturbing, these patients were working in clerical posts.

Nature of previous operations:

The population was studied to see if they were operated before, as described above. The choice of operative procedure was noted. Of the 30 patients operated before recruitment for the study, only 2 had a seton placed. One patient had a hemorrhoidectomy, mentioned for possible trauma to the internal sphincter and the remaining had fistulectomy /

fistulotomy operations (It was not possible to differentiate the above two based on history or notes). In patients where more than one operation was done in the past this was noted on the spread sheet.

Change in pressures:

A. All patients in the given population.

Average resting anal pressure –

Pre operative – Mean -136.1 (SD 50.42) cm water

Post operative – Mean -127.9 (SD 35.27) cm water

This data suggests a drop in the resting sphincter pressure of about 8 cm of water after division of the internal sphincter, in keeping with the evidence in literature. However, when the tests for significance are applied –

Paired t test = 0.986, P value of 0.326

Wilcoxon z test = -1.122, P value of 0.262

Such a p value indicates that ***the drop in resting anal pressures of about 8 cm of water, though in keeping with published literature and simple reasoning, is not a statistically significant finding.***

Average Squeeze pressure –

Pre operative – Mean - 238.9 (SD 88.5) cm water

Post operative – Mean - 243.1 (SD 70.3) cm water

This data suggests a rise in the average squeeze pressures. This may be due to the theory that the puborectalis muscle compensates compromised function of the other external sphincter muscles.

Paired t test = -0.32, P value of 0.74

Wilcoxon z test = -0.269, P value of 0.79

This indicates that the increase in pressure seen in the post operative squeeze pressures of approximately 4 cm of water is not of statistical significance.

Fistula type subdivided further into anatomical type.

The data was then divided into the types of fistula treated. As we saw in the baseline data, there were *supra sphincteric and trans sphincteric fistula.* The trans sphincteric fistula were divided into both *high and low trans sphincteric.*

The numbers of the supra sphincteric fistula were small, and studied separately.

The trans-sphincteric were of particular interest as the treatment options for both high and low trans-sphincteric are different. Hence the pressure difference in the high and low trans-sphincteric was studied. The results are tabulated as shown below for resting pressures.

Trans sphincteric (TS) type	**Pre / post operative**	**Resting pressures (with standard deviation SD)** cm of water	**Wilcoxon Z test**	**p value**
High TS	Pre op	140 (SD 45.3) cm	----------	--------
High TS	Post op	129 (SD 37.8) cm	-1.39	0.162
Low TS	Pre op	136.1 (54.5) cm	----------	-------
Low TS	Post op	126.1 (33.8) cm	-0.572	0.568

Table 1 – Resting pressures compared in both low and high trans-sphincteric fistula

A similar exercise was done for the fistula of low trans sphincteric and high trans sphincteric type with the squeeze pressures. This as described earlier is a function of the somatic external sphincter.

Trans sphincteric (TS) type	**Pre / post operative**	**Squeeze pressures (with standard deviation SD)** cm of water	**Wilcoxon Z test**	**P value**
High TS	Pre op	235.3 (SD 69.9) cm	----------	--------
High TS	Post op	240.3 (SD 64.5) cm	-0.363	0.712
Low TS	Pre op	246.7 (104.8) cm	----------	-------
Low TS	Post op	245.3 (76) cm	-0.274	0.784

Table 2 – Squeeze pressures compared in both low and high trans-sphincteric fistula

As the data in this series do not follow normal distribution, the Wilcoxon Z test was chosen for the analysis. On analysis the data reveal that there exists ***no statistical significance in the drop of pressures before and after conventional surgery, when fistulae are subdivided into low and high trans-sphincteric fistula.***

STATISTICAL ANALYSIS OF WEXNER SCORES AND CHANGE AFTER TREATMENT

The Wexner score was the score used for incontinence in this study.

The data obtained was analyzed and the following results obtained.

Pre operative Wexner score.

Range – Minimum score 0 to Max score 8

Median Wexner – score 0

Post operative Wexner score

Range – Minimum score 0 to Max score 10

Median Wexner – score 1

Wilcoxon Z score = 4.321 (p value = < 0.001)

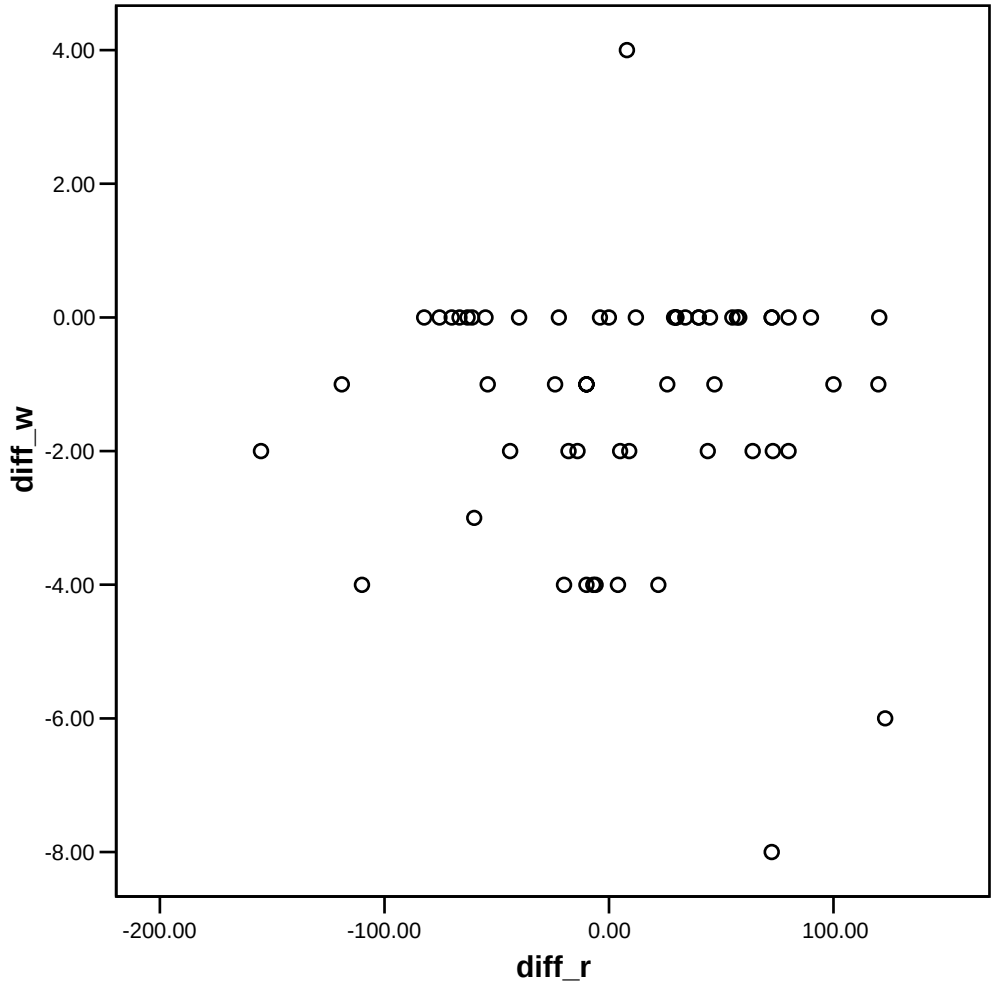
In the study population, there was a change in the median Wexner score from pre operative values to post operative values by 1 point. The change in Wexner was analyzed and the p value was found to be <0.001. **This indicates that the change in Wexner score of 1 point was statistically significant.**

A similar exercise was followed for low trans sphincteric fistula and high trans sphincteric fistula separately and the score difference was **1** in each group. Thus the change in Wexner score was the same in both low trans-sphincteric and high trans sphincteric fistula.

Correlation between resting pressure and Wexner scores

A scatter plot was constructed to see the relation between changes in resting pressures and changes in the Wexner score. The output graph is

shown. The Spearman's correlation test, when done for the given data reveals a co-efficient of 0.05, p value 0.73. This implies that there is no statistically significant relationship between the change in resting pressures before and after conventional fistula surgery and Wexner scores used for the same patients. Hence anal manometry does not predict those patients who become incontinent.



Graph 1
Scatter plot – X axis showing changes in resting pressure, Y axis showing changes in Wexner score. Changes calculated as difference in preoperative values from post operative values.

Did previous operation affect present outcome?

One of the Aims of the study was to determine the factors that affected fistula outcome. The history of a previous operation for fistula was studied as a possible variable that may predict incontinence.

As we had seen in the baseline data, 30 patients out of the 57 had had some form of a previous operation.

Previous operation status	Difference in resting pressure	Difference in squeeze pressures
No (n=27)	3.83 (SD 56.6)	-11.14 (SD 87.07)
Yes (n=30)	11.95 (SD 67.31)	2.01 (SD 109.73)

Table 3 –Comparison of previous operation status and relation with changes in anal manometry.

Both resting and squeeze pressures were studied and no significant difference was found between either resting (p value 0.533) or squeeze pressures (p value 0.598) in patients that had recurrent fistula, compared to those who presented for their first operation.

Correlation of anal pressures with social quality of life:

The changes in anal resting pressures were plotted against the data given by patients, compiled to see if they had to make a social alteration in their life or if incontinence affected their quality of life.

Social problems range from difficulty in public life, need to use sanitary pads or torn cloth to collect leaking stool. As these results would correlate with a questionnaire, it was interesting to see if a change in anal canal pressures correlated with these social problems.

	soc prob	N	Mean Rank	Sum of Ranks
Diff in resting pressure	No	50	28.62	1431.00
	Yes	7	31.71	222.00
	Total	57		
Diff in Wexner scores	No	50	31.37	1568.50
	Yes	7	12.07	84.50
	Total	57		
Diff. in squeeze pressure	No	50	29.06	1453.00
	Yes	7	28.57	200.00
	Total	57		

Table 4 –Table that compares social function versus anal manometry and Wexner scores.

Test Statistics(b)

	Dif in rest pressure	Difference in Wexner	Diff in squeeze pressure
Mann-Whitney U	156.000	56.500	172.000
Wilcoxon W	1431.000	84.500	200.000
Z	-.462	-3.066	-.073
Asymp. Sig. (2-tailed)	.644	.002	.942
Exact Sig. [2*(1-tailed Sig.)]	.660(a)	.002(a)	.953(a)

a Not corrected for ties.
b Grouping Variable: social problems

Table 5 –Table with tests of significance for the above comparison (in table 4), comparing social outcomes with anal pressure changes and Wexner scores.

The social quality of life question, revealed as displayed above a 12.3% (7 out of 50) prevalence of incontinence post operatively. There was no statistical significance between the change in anal pressure and social quality of life assessment. It needs to be stated here, that a detailed quality of life questionnaire was not used.

CONCLUSIONS

- **Aim: To determine the percentage of patients who suffer from impaired continence after anal fistula operations.**

1. Incontinence is not uncommon after fistulotomy for fistula in ano. The rates of incontinence based on Wexner scores indicate that up to 50% of patients suffer from some degree of incontinence. Only 12 % of these patients are socially troubled by incontinence.

- **Aim: Determine the predisposing factors that increase the risk of sphincter damage and incontinence.**

2. Anal manometry values alone are unable to predict patients who will complain of fecal incontinence.
3. The study aimed to look at certain risk factors for incontinence. The parameters of type of fistula and previous operation were not significant risk factors. There were inadequate women in the study population to make a comment on sex as a predictor of incontinence. These may be addressed in a larger study along with other predictors.

- **Aim: To identify a) those patients who are likely to sustain sphincter damage as well as b) those patients who will be**

successfully cured from disease without suffering sphincter damage.

4. Anal manometry and Wexner scores can be used to evaluate patients preparing for conventional fistula surgery, and have a role to play in quantification of incontinence. Anal manometry readings show changes in resting pressures that are possibly compensated by the puborectalis sling to maintain continence. The Wexner scores also show a significant drop after operation.
5. Changes in Wexner scores from before and after anal fistula surgery indicate a significant change, irrespective of whether the fistula is low or high trans sphincteric in nature.
6. The percentage of patients who were successfully cured from the disease without sustaining sphincter damage was not determinable as no statistically significant drop was measured in sphincter pressures pre operatively or after operation.

- **Additional observations:**

7. There is a suggestion of increased sphincter pressures post operatively high in the anal HPZ (about 40mm). The pressure changes, at this point are statistically significant between preoperative and postoperative values. This may be due to

puborectalis muscle compensation, and this requires further investigation.

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APPENDIX

Appendix -1

THE WEXNER SCORE

Type of incontinence	*Never*	*Rarely*	*Sometimes*	*Usually*	*Always*
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Never, 0; rarely, <1/month; sometimes, <1/week, 1/month; usually, <1/day, 1/week; always, 1/day.

0, perfect; 20, complete incontinence.

Appendix 2 –

The American Medical Systems score

	Never	Rarely	sometimes	Weekly	Daily	Several times a day
Did you experience accidental bowel leakage of gas?	0	1	7	13	19	25
Did you experience minor bowel soiling or seepage?	0	31	37	43	49	55
Did you experience significant accidental bowel leakage of liquid stool?	0	61	73	85	97	109
Did you experience significant accidental bowel leakage of solid stool?	0	67	79	91	103	115
Has this accidental leakage affected your lifestyle?	0	1	2	3	4	5

Several times daily, >1 episode a day; daily, 1 episode a day; weekly, 1 or more episodes a week but <1 a day; sometimes, >1 episode in the past four weeks but <1 a week; rarely, 1 episode in the past four weeks; never, 0 episodes in the past four weeks.

Appendix 3 –

Equipment -

Water filled closed system balloon, attached to a polygraph.

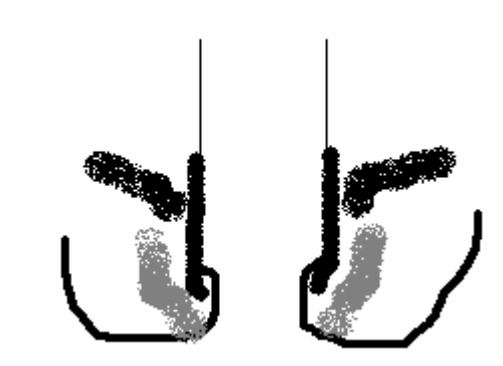
	Photograph of anal manometer to be inserted.	

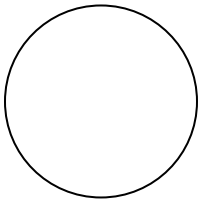
Appendix 4-

Patients Name: Hospital number: Study ID:

Contact address –full postal phone No. e-mail id.

DIAGRAMATIC REPRESENTATION





1. History of any Anorectal surgery in the past with dates.

2. Wexner score (preoperative)–

3. Treatment done –

   Senior consultant / other

4. Physiology – resting anal pressure maximal anal squeeze pressure

   lev1

lev2

lev3

lev4

lev5

AFTER 3 MONTHS.

1. Physiology – resting anal pressure maximal anal squeeze pressure

   lev1

   lev2

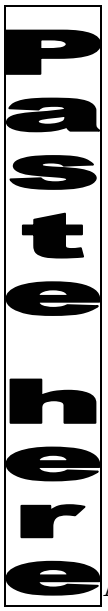
   lev3

   lev4

   lev5

2. Wexner score –

3. Clinically – how is the disease?



Anal manometry trace.

INFORMED CONSENT

Date:

I , Son/daughter of have clearly understood that I am a participant in a study that will determine if I or others with a similar disease as I have will have a change in continence after conventional surgery for fistula in Ano. The nature of the disease- fistula in ano has been explained to me and the type of surgery that I will need is something I understand.

I understand that I need an operation for this condition and the fact that I am in this study will not influence the type of surgery I have. I am willing to go through the series of tests and answer questions that relate to my ability to continence. I know that these tests will only asses the strength of my anal muscles and are not a part of my final treatment.

I am aware that I can withdraw from this study at any point and that it will have no bearing on the planned course of my treatment. I am assured that the doctors will keep me informed as to when I need to follow up and I will try to follow their recommendations as far as possible.

Witness- Patients signature:

Pt Id	Pre/Post	RP1	RP2	RP3	RP4	RP5	SQ1	SQ2	SQ3	SQ4	SQ5	CG1	CG2	CG3	CG4	CG5	WEXNER
889915C	Pre	**70**	60	70	90	60	**140**	130	130	140	120	**150**	140	150	150	130	0(20)
889915C	PO	**77**	88	111	144	122	**122**	144	177	233	222	**77**	111	155	200	188	1(20)
872092C	Pre	**77.7**	111	66			**311**	266	100			**144**	155	111			0(20)
872092C	PO	**110**	160	70	30		**360**	350	210	50		**230**	220	160	90		0(20)
570714C	Pre	**111**	77	77	66		**266**	333	277	211		**400**	377	333	322		0(20)
570714C	PO	**116**	125	100	66	16	**150**	350	300	283	200	**175**	366	366	350	336	2(20)
702611A	Pre	**60**	80	130	120	80	**130**	150	160	180	140	**120**	160	170	170	120	0(20)
702611A	PO	**80**	100	150	100	80	**100**	170	260	150	160	**120**	160	270	200	180	4(20)
584344C	Pre	**170**	160	150	140	110	**280**	290	290	260	230	**300**	280	310	270	310	0(20)
584344C	PO	**81**	90	118	136	109	**118**	172	181	209	200	**136**	181	200	236	218	0(20)
667521C	Pre	**163**	62.5	12.5			**263**	150	75			**213**	100	62.5			0(20)
667521C	PO	**60**	72	90	27		**190**	190	154	36		**163**	172	163	136		8(20)
988892C	Pre	**50**	66	141	183	141	**83**	133	208	225	200	**91**	108	150	200	150	2(20)
988892C	PO	**109**	127	190	227	72	**163**	190	227	254	145	**136**	154	236	236	209	4(20)
838405C	Pre	**130**	140	110	90		**230**	210	190	180		**210**	220	230	220		0(20)
838405C	PO	**80**	110	100	40		**230**	300	270	220		**210**	220	220	150		0(20)
419735B	Pre	**160**	190	250	200	130	**190**	390	400	360	240	**180**	380	390	370	340	0(20)
419735B	PO	**118**	127	109	72	54	**409**	409	390	363	318	**400**	400	381	318	300	6(20)
848610C	Pre	**70**	60	60	60		**90**	90	110	110		**60**	80	80	70		0(20)
848610C	PO	**75**	87.5	100	125	113	**87.5**	100	138	200	200	**75**	113	113	138	150	0(20)
026198D	Pre	**72**	154	163	145	81	**290**	300	290	209	145	**100**	290	245	236	190	2(20)
026198D	PO	**58**	75	66	83	66	**83**	200	216	208	141	**91**	233	200	200	150	4(20)
787627C	Pre	**81.3**	162	187			**118**	187	206			**100**	143	175			0(20)
787627C	PO	**66.6**	55.5	44.4			**111**	100	88.8			**100**	88.8	77.7			0(20)
054341D	Pre	**75**	175	133	91	25	**141**	241	266	175	58	**233**	325	300	150	100	6(20)
054341D	PO	**100**	140	110	100	60	**130**	290	180	200	90	**190**	420	240	160	150	10(20)
984050C	Pre	**50**	130	180	140	100	**120**	210	280	270	160	**80**	180	210	180	140	4(20)
984050C	PO	**63**	54	72	172	54	**109**	109	136	227	127	**81**	63	81	181	118	0(20)
885833C	Pre	**140**	100	110	110	190	**200**	200	270	230	290	**170**	270	280	300	200	0(20)
885833C	PO	**77**	88	111	133	111	**111**	155	177	222	188	**122**	133	266	300	200	0(20)

843841C	Pre	**77.7**	55.5	33.3	44.4		**267**	200	167	133		**167**	122	88.8	77.7		0(20)
843841C	PO	**70**	90	100	50		**370**	350	370	210		**330**	260	240	150		0(20)
863925C	Pre	**130**	90	80	60		**350**	270	190	140		**210**	180	150	150		0(20)
863925C	PO	**100**	140	130	90		**260**	340	310	260		**120**	250	190	150		1(20)
805047C	Pre	**12.5**					**100**	42.8	14.2			**100**	85.7	57.1	0	0	0(20)
805047C	PO	**88**	77	77	66		**188**	155	144	111		**133**	122	111	122	0	0(20)
885861C	Pre	**100**	120	130	90	0	**190**	190	200	210	0	**140**	150	160	170	0	0(20)
885861C	PO	**140**	120	130	80	0	**210**	220	200	150	0	**180**	190	170	189	0	1(20)
699170A	Pre	**70**	90	90	50		**140**	180	140	110		**100**	140	120	90		0(20)
699170A	PO	**81**	145	209	145	54	**109**	190	300	245	82	**118**	163	227	236	118	1(20)
849219C	Pre	**155**	122	77	66		**300**	255	177	111		**222**	100	155	155		0(20)
849219C	PO	**100**	55	55	44		**166**	111	111	111		**188**	133	122	122		0(20)
036102D	Pre	**63**	145	190	227	100	**118**	218	245	263	145	**145**	172	236	272	190	8(20)
036102D	PO	**130**	180	170	110	80	**210**	210	190	200	210	**180**	190	200	190	90	9(20)
970995C	Pre	**110**	150	140	110	80	**250**	290	290	210	210	**290**	310	280	220	200	0(20)
970995C	PO	**81**	127	145	72	54	**209**	272	272	190	118	**227**	290	309	236	209	2(20)
821158C	Pre	**163**	125	62.5			**250**	225	188			**200**	200	113			0(20)
821158C	PO	**50**	90	90	30		**90**	170	270	240		**60**	180	180	140		0(20)
656613C	Pre	**50**	37.5	37.5	25	25	**87.5**	87.5	62.5	50	50	**138**	150	138	150	150	0(20)
656613C	PO	**110**	90	60	40		**220**	220	180	110		**130**	130	140	100		3(20)
700220C	Pre	**40**	70	70	60	50	**50**	80	110	130	110	**60**	80	90	90	90	0(20)
700220C	PO	**61**	107	131	53	5	**92**	246	238	166	61	**107**	201	184	153	100	0(20)
686273C	Pre	**180**	120	50			**260**	260	80			**0**					2(20)
686273C	PO	**60**	50	20			**180**	140	80			**0**					3(30)
003554D	Pre	**100**	180	90	70		**140**	380	280	230		**300**	370	330	300		0(20)
003554D	PO	**83**	116	116	75	58	**108**	241	275	175	141	**133**	225	283	233	200	2(20)
893321C	Pre	**100**	122	177	188		**144**	255	377	300		**122**	366	277	255		0(20)
893321C	PO	**100**	130	110	100	60	**180**	280	220	210	130	**190**	230	230	170	70	0(20)
857231C	Pre	**100**	90	100			**130**	110	100			**120**	120	90			0(20)
857231C	PO	**167**	100	77.7			**200**	144	111			**178**	122	111			0(20)
996288C	Pre	**90**	154	118	63	27	**190**	245	236	200	81	**218**	254	245	236	127	2(20)
996288C	PO	**63**	81	81	36	18	**200**	290	272	190	54	**154**	272	300	209	118	4(20)

978905C	Pre	**60**	90	130	130	70	**80**	110	170	170	150	**70**	100	140	160	140	4(20)
978905C	PO	**63**	109	136	90	100	**109**	145	163	136	154	**81**	118	154	118	136	8(20)
891134C	Pre	**90**	140	170	170	210	**110**	180	300	360	370	**130**	220	280	260	220	0(20)
891134C	PO	**90**	90	130	120	130	**110**	120	150	180	200	**100**	150	160	160	150	0(20)
940885C	Pre	**60**	70	70	70		**60**	80	90	100		**50**	70	100	110		0(20)
940885C	PO	**100**	110	140	130		**140**	190	310	300		**180**	290	380	380		0(20)
913709C	Pre	**180**	100	80	40		**240**	150	110	50		**330**	240	250	160		0(20)
913709C	PO	**90**	106	109	136	72	**109**	127	127	154	81	**163**	190	200	200	181	2(20)
974622C	Pre	**109**	145	163	109	27	**318**	336	336	268	63	**290**	290	281	200	100	4(20)
974622C	PO	**83**	75	141	100	83	**108**	216	358	341	291	**91**	250	350	300	225	8(20)
618571C	Pre	**60**	140	140	50		**150**	300	250	120		**100**	222	160	110		0(20)
618571C	PO	**40**	30	30	25		**120**	120	120	90		**80**	80	80	100		1(20)
906299C	Pre	**90**	80	60	70		**280**	260	210	180		**230**	160	140	150		0(20)
906299C	PO	**90**	50	80	40	40	**150**	110	120	80	60	**120**	70	110	80	80	0(20)
906299C	Pre	**90**	50	80	40	40	**150**	110	120	80	60	**120**	70	110	80	80	0(20)
906299C	PO	**100**	80	30	20		**150**	180	40	20	230	**190**	100	90			4(20)
833644C	Pre	**25**	12.5				**100**	87.5	87.5			**100**	75	50			0(20)
833644C	PO	**90**	160	170	180	160	**140**	230	250	350	340	**100**	280	320	300	270	2(20)
707359C	Pre	**30**					**70**	50	20			**70**	40	30			2(20)
707359C	PO	**90**	120	140	100	70	**150**	160	170	140	130	**80**	180	180	150	150	6(20)
906800C	Pre	**120**	110	120	130		**170**	200	310	280		**120**	180	280	260		0(20)
906800C	PO	**70**	60	90	90	90	**80**	90	130	130	130	**60**	80	140	140	140	0(20)
906800C	Pre	**70**	60	90	90	90	**80**	90	130	130	130	**60**	80	140	140	140	0(20)
906800C	PO	**70**	130	120	100		**180**	240	240	160		**130**	180	170	210		0(20)
893222C	Pre	**120**	70	70	50		**200**	150	100	70		**120**	110	100	120		0(20)
893222C	PO	**80**	80	90	50	30	**180**	160	160	120	110	**110**	120	140	160	90	0(20)
962942C	Pre	**50**	100	130	90		**80**	130	170	160		**70**	120	150	110		0(20)
962942C	PO	**154**	127	63	45		**190**	181	154	100		**163**	163	127	90		1(20)
005217D	Pre	**139**	127	136	154	45	**227**	227	300	309	245	**218**	190	318	300	127	4(20)
005217D	PO	**63**	109	54	36	54	**90**	154	281	309	300	**100**	227	290	263	296	4(20)
834083C	Pre	**125**					**188**	62.5	25			**100**	87.5	37.5			0(20)
834083C	PO	**133**	144	144	188		**211**	277	322	366		**188**	244	266	277		0(20)

853450C	Pre	**180**	110	70	40		**290**	240	190	110		**220**	150	120	100		0(20)
853450C	PO	**60**	70	70	90	50	**170**	250	320	270	200	**100**	90	130	130	80	0(20)
184981C	Pre	**170**	120	120	60		**280**	300	380	280		**240**	210	250	150		0(20)
184981C	PO	**122**	88	88	166	44	**177**	188	200	244	188	**211**	200	177	200	100	4(20)
904387C	Pre	**110**	160	210	160		**160**	260	310	260		**130**	220	270	220		0(20)
904387C	PO	**113**	138	138	138	87.5	**200**	238	188	175	100	**150**	163	175	188	113	0(20)
881108C	Pre	**140**	100	80			**210**	170	170			**130**	150	140			0(20)
881108C	PO	**144**	111	55			**166**	177	144			**155**	144	122			0(20)
899582C	Pre	**90**	60	80	160		**130**	110	110	90		**90**	70	90	180		0(20)
899582C	PO	**60**	110	110	120	70	**180**	230	290	300	260	**160**	210	310	200	200	0(20)
687046C	Pre	**180**	110	100	0	0	**360**	300	260	0	0	**NR**	0	0	0	0	3(20)
687046C	PO	**127**	109	154	27	0	**236**	218	236	40	0	**172**	145	172	118		4(20)
785473C	Pre	**60**	60	110	90	80	**150**	110	170	150	170	**90**	120	150	180	140	4(20)
785473C	PO	**64**	100	128	100	71	**92**	135	227	150	100	**100**	150	236	192	171	6(20)
785473C	Pre	**64**	100	128	100	71	**92**	135	227	150	100	**100**	150	236	192	171	6(20)
785473C	PO	**83**	116	108	83	50	**116**	158	166	125	91	**125**	191	175	166	125	6(20)
021275D	Pre	**150**	160	170	100	70	**360**	350	330	330	160	**200**	220	210	230	200	0(20)
021275D	PO	**133**	141	108	50	33	**250**	266	300	225	191	**150**	150	158	158	91	0(20)
044082D	Pre	**100**	118	136	127	100	**172**	172	172	190	145	**209**	181	209	227	190	2(20)
044082D	PO	**63**	90	127	100	63	**90**	109	163	172	118	**72**	118	172	136	145	4(20)